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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,928	01/22/2004	Michael P. McCarthy	469201-716	5745
7590	03/29/2006		EXAMINER	
Raymond J. Lillie, Esq. c/o Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein 6 Becker Farm Road Roseland, NJ 07068			SALIMI, ALI REZA	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 03/29/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/762,928	MCCARTHY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	A R. Salimi	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 March 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment filed 03/08/2006. Claims 1-7 are pending before the examiner.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 03/08/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of patents 6,962,777; 6,415,945; 6,261,765 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Rejections - 35 USC § 112***

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced in the previous Office Action mailed 9/27/05. Applicants argue that the method is not limited to specific methods of disassembling and reassembling papillomavirus VLPs. Moreover, Applicants assert that specification presents the conditions. In addition, Applicants assert that addition of steps would be contrary to the interest of justice, because Applicants and only Applicants are the first to discover that one may produce purified papillomavirus VLPs by purifying disassembled VLPs and then reassembling the disassembled VLPs.

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Regarding claim 7 Applicants assert that while claim 5 does not define any conditions for reassembly of disassembled VLPs, claim 1 does include the step and there is antecedent basis for reassembly of the disassembled VLPs as defined in claim 7.

Applicant's argument as part of amendment filed 03/08/2006 has been considered fully, but they are not persuasive.

Applicants are reminded that, although, the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 1 is incomplete for omitting essential steps, such omission amount to a gap between the steps. Method claim should be clear and without any gaps. Just because the scope of the method claim is broad it does not mean it can omit essential steps. Presently, claim 1 is rather confusing because none of essential steps have been stated. The method steps do not happen in a vacuum. Furthermore, the "interest of justice" argument advanced by the Applicants is at best tenuous. The interest of justice does not relieve Applicants from drafting appropriate claims that comply with the well-settled rules, and statutes. Applicants are not the only ones that have discovered VLP purification. Applicants have only optimized a condition that would lead to reassembly of papillomavirus VLPs and for that have already received multiple patents. The interest of justice is best served when Applicants claim and obtain what is appropriate patent eligibility. The rejection is maintained.

Regarding Claim 7, Applicants' argument is misplaced. Claim 7 lacks insufficient antecedent basis. Claim 5 only further limits the claim 1 and has nothing to do with the subject matter as defined in claim 7. The rejection is maintained.

***Claim Rejections - 35 USC § 102***

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Salunke et al (Cell, 1986, Vol. 46, pages 895-904) for reasons of record advanced in the previous Office Action mailed 9/27/05. Applicants argue that Salunke et al discloses the expression of VP1 capsid protein, and then capsid protein is purified by precipitation at low ionic strength. Applicants assert Salunke does not produce purified papillomavirus like particles (VLPs).

Applicant's argument as part of amendment filed 03/08/2006 has been considered fully, but they are not persuasive.

Applicants understanding of the teaching of Salunke et al is misplaced. It does not matter whether the cited reference taught low ionic or high ionic strength because claim 1 is so broadly drafted that includes all conditions, and the purification step is indeed taught by the cited art. The broad limitations of the claim is clearly anticipated by the teaching of Salunke et al. As stated before Salunke taught purification of disassembled polyomavirus (see page 903, left column, 1<sup>st</sup> full paragraph and 2<sup>nd</sup> paragraph, also see page 897, right column first full paragraph). The rejection is respectfully maintained.

No claims are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

3/28/06



ALI R. SALIMI  
PRIMARY EXAMINER